

Information letter and declaration of consent for guardians of children aged 0 - 16

Background

On behalf of the Ministry of Health and Care Services, the Western Region Health Authority has, in partnership with the Southern and Eastern Regional Health Authority, established the Norwegian Registry of Cleft Lip and Palate. The aim is to ensure that treatment results are documented. In order to provide the best possible treatment and follow-up, better information is needed concerning not only the condition of each individual patient with a cleft lip and palate, but also the entire patient group. The Norwegian Registry of Cleft Lip and Palate will make an important contribution to research. To optimise the range of treatment services offered to patients, quality assurance and research are both important and essential.

It is voluntary to allow the child to be registered. Informed consent will also be required. This means that you must sign a declaration of consent before we can register information about your child in the registry.

What information will be registered in the registry and where will it be obtained from?

The information entered in the registry consists of your name and national ID number, as well as information concerning your diagnosis and treatment. Limited information is registered concerning other illnesses, hereditary conditions, function and adaptation.

The data consist of systematised information which is normally recorded in the child's medical records during treatment and follow-up. We will contact you if we find that any information is missing from the registry concerning admissions/consultations.

Storage and distribution of information

Information is registered using computer technology and is secured against access by unauthorised persons. The information is permanently stored in electronic form.

The processing of the information has been approved by the Norwegian Data Protection Authority in accordance with Section 33 of the Personal Data Act and Section 5 of the Health Register Act. Bergen Hospital Trust is the official controller. All information that is collected is treated confidentially, and everyone who is involved in the registry in some way as part of their work is subject to a duty of confidentiality concerning any circumstances they become aware of.

Medical professionals treating the patient group can obtain information from the registry concerning the patients that are treating personally. Information concerning patients other than those which the person concerned has treated may be released upon application to the board, but the release of such information must be approved by statutory bodies (data protection officer, regional committee for medical research ethics). Relevant information will be distributed between the professional groups when required for professional purposes. Anonymised mass information from the registry will be presented in standard annual reports to professional arenas, the patient group and the health authorities.

Right of access, alteration and deletion of information

You have full right of access to the information that is registered about your child and to have any errors corrected. You can also ask for information about your child to be deleted from the registry at any time, without giving any reason.

The deletion of data will not result in deletion from anonymised research files which have already been used for research purposes. Your child's treatment will not be affected in any way if you decide not to allow the child to be registered or if you subsequently wish to withdraw your consent. Once your child has reached the age of 16, they will need to decide for themselves whether or not they wish to be included in the registry. If desired, they can ask for information registered about them to be deleted.

Research

Information will only be distributed for research into cleft lip and palate in the form of de-identified summaries. In other words, the information will be processed without any names or national ID numbers or other directly recognisable information. A code links the child to their associated information through a list of names. Only authorised personnel linked to the registry will have access to this list and be able to trace the information back to the child concerned.

For research projects, it may be appropriate to collate information from the registry with other information in the child's medical records and with official registers and population surveys, such as: Medical Birth Registry of Norway, Norwegian Patient Registry, Norwegian neonatal medical quality register, Cancer Registry of Norway, Norwegian Prescription Database, registers under Statistics Norway, registers under the Norwegian Labour and Welfare Administration (NAV), Cause of Death Register, the Norwegian quality register for the mental health of newborn babies and young children and National school examinations.

The information will only be collated with information from the Norwegian Patient Register in order to calculate the registry's degree of coverage. However, all research projects must be approved in advance by the regional committee for medical research ethic and other official bodies as required by the law.

For more information:

www.helse-bergen.no/LKG

E-mail: lkg-registeret@helse-bergen.no

PATIENT DATA:

NATIONAL ID NUMBER:

FULL NAME First name Middle name(s)
Surname:

TREATMENT TEAM (insert cross)
OSLO
BERGEN

SIGNING OF DECLARATION:

I have read the above information and
consent to:

The abovementioned information being
registered in the patient database. (Please insert
cross)

The information may be used for research
purposes as mentioned above. (Please insert
cross)

**PLACE
DATE**

**GUARDIAN 1:
TELEPHONE/MOBILE:**

**GUARDIAN 2:
TELEPHONE/MOBILE:**

The consent of one guardian will be sufficient.